PRODUCT USER MANUAL

Nitrile glove

PPE – Category III complex design

Brand	Code	Description
Hand Safe	GN99	Powder free nitrile – blue colour

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GN99 Product User Manual

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2. Revision Record

Revision Number	Detail of change	Date of Issue	Document Change Note Number
1	New Document	23 August 2013	

Product Description and Certification

Product Type	Disposable examination nitrile gloves
Product Classification	PPE – Category III complex design
Generic Description and Purpose	- Suitable for general purpose use, medical use and food contact. - Waterproof glove with low chemical protection, as defined in EN374-1 : protective gloves against chemicals and micro-organisms.

Hand Safe nitrile examination gloves (GN99)

HPC Healthline UK Ltd declares that the PPE described hereafter:

» is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard:

BS EN 420:2003 + A1:2009	Protective gloves – general requirements and test methods
BS EN 347-1:2003	Protective gloves against chemicals and micro-organisms - Terminology and performance requirements
BS EN 347-2:2003	Protective gloves against chemicals and micro-organisms - Determination of resistance to penetration
BS EN 347-3:2003	Protective gloves against chemicals and micro-organisms - Determination of resistance to permeation

» Is identical to the PPE which is the subject of EC certificate of conformity no. CE 585141 issued by British Standards Institute Group (BSi Group), Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP, United Kingdom.

» Is subject to the procedure set out in Article 11 point A of Directive 89/686/EEC under the supervision of the approved body British Standards Institute Group (BSi Group), Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP, United Kingdom, under CE 585148 article 11A.

3. Performance Levels

Article 10 Certificate: CE 585141 (BSI Group)

EC Type Examination Test Data:

EN420:2003+A1:2009	Dexterity	level 5
EN374-2:2003	Resistance to penetration	level 2 AQL 1.5
EN347-3:2003	Resistance to permeation	
	40% Sodium hydroxide (K)	level 6
	n-Heptane (J)	level 1
EN388:2003	Abrasion resistance	level 0
	Blade cut resistance	level 0
	Tear resistance	level 0
	Puncture resistance	level 0

The GN99 Hand Safe Nitrile Gloves satisfy the requirements:

- For waterproof and low chemical protection gloves (EN374-3:2003)
- For micro-organism resistant gloves (EN374-2:2003) – level 2

Performance Level and Pictogram Narrative:

Permeation requirements for BS EN 374-3:2003 necessitate a level 2 performance for three chemicals tested from the list detailed in BS EN 374-1:2003.

The fuming flask pictogram would be accompanied by the letter code of each chemical to which the product gained a level 2 performance.

Should a glove not meet the requirements of permeation it can be considered waterproof and be labelled with the beaker pictogram for waterproof and low chemical risk but it must meet the requirements of BS EN 374-2:2003 and BS EN 420:2003

A glove shall be considered to form an effective barrier to micro-biological hazards when it conforms to at least level 2 of the penetration test of annex A of EN374-2:2003

EN374-3:2003 Breakthrough times and list of test chemicals

Breakthrough time - min	Permeation performance level
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

Code Letter	Chemical	CAS Number	Class
A	Methanol	67-56-1	Primary alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile compound
D	Dichloromethane	75-09-2	Chlorinated paraffin
E	Carbon Disulphide	75-15-0	Sulphur containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofurane	109-99-9	Heterocyclic and ether compound
I	Ethyl acetate	141-78-6	Ester
J	n-Heptane	142-85-5	Saturated hydrocarbon
K	Sodium Hydroxide	1310-73-2	Inorganic base
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid

BS EN 374-2:2003 for penetration necessitates that the gloves shall not leak when tested with air and water. For type testing one glove of each size shall be tested with an overall minimum of 4 gloves. For production control, gloves from a single lot or batch shall be sampled and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall comply with those given in the table below or as agreed between the purchaser and seller, if the latter is more stringent.

Performance level	Acceptable quality level unit	Inspection levels
Level 3	< 0.65	G1
Level 2	< 1.5	G1
Level 1	< 4.0	S4

4. User and Storage Information

User information is displayed on the inner dispenser and outer case. The information appears as both written instruction and pictograms. The user information and relevant pictograms are detailed in the table below.

- Product brand name
- Description of product
- Product code
- Product size
- Quantity in the dispenser and case
- CE mark and reference of directive (notified body number)
- Lot number
- Name and address of the manufacturer
- Expiry date
- Country of origin
- Bar code (for both inner and outer case)
- The gloves are powdered or powder free
- The gloves contain accelerators ZDEC and ZDBC
- The packaging is recyclable

- Usage instructions:
  - » Do not re-use / single use only (see section 9 for the pictogram)
  - » Safe for food use
  - » Waterproof and low chemical protection
  - » Micro-organism resistant

- Storage instructions:
  - » Store in a cool dry place (see section 9 for the pictograms)
  - » Away from direct sunlight or fluorescent light (see section 9 for the pictograms)

Pictograms:

Symbol	Description		Symbol	Description
CE 0086	CE Mark confirming that products follow requirements of EU Directive 89/686/EEC (Personal Protective Equipment)			Manufacturer
	Single use only			Date of manufacture
	Keep in a cool dry place			Use by
	Keep away from direct sunlight or fluorescent light		LOT	Lot number
	Some elements of the product and/or packaging are recyclable			Product can be used with the food industry according to the European Regulation 1935/2004
EN374-3:2003	EN374 – waterproof gloves and low chemical protection		EN374-2:2003	EN374 – protection against biological hazards
5°C 25°C	Store at temperatures no less than 5°C and no more than 25°C		LATEX	Latex free

Additional Symbols used by HPC Healthline:

AQL 1.5	Acceptable Quality Level of 1.5		POWDER	Powder free
EN420 EN374 CAT III	PPE classification and standards		CE Class 1 Medical Device	Class I Medical Device

Product Efficacy and Usage:

- The physical properties of the nitrile glove can be altered through the effects of storage (temperature, light and ozone exposure) and were tested under laboratory ambient conditions.
- The gloves met the requirements of waterproof and low chemical resistance gloves.
- The gloves do not provide protection against mechanical risk (abrasion, blade cut, tear and puncture)
- The gloves do not provide protection against cold
- The gloves do not provide protection against heat
- The gloves do not provide protection against electricity
- The gloves are disposable and must be discarded following use. They cannot be cleaned and used a second time as this will affect the protective properties of the glove.
- The gloves should not be used after the expiry date printed on the box (three years following date of manufacture).
- The gloves must not be used should the nitrile film be cracked, hardened or display pin holes / tears.

Allergy statement:

The GN99 nitrile disposable examination gloves contain carbamate accelerators (ZDBC and ZDEC) which can cause type IV skin irritation and contact dermatitis.

Storage:

The GN99 nitrile disposable examination glove properties can be affected by extremes of temperature, light and ozone exposure. Therefore it is recommended that the gloves are stored in a dry atmosphere between the temperatures of 5°C and 25°C, away from direct sunlight, fluorescent light or sources of ozone.

Disposal:

The GN99 nitrile gloves can be disposed of through normal household waste at approved landfill sites, or by high temperature incineration, using licensed contractors. Disposal must be in accordance with local authority and national regulations.

Ecological information:

The GN99 nitrile gloves are not readily biodegradable.

Transport:

The GN99 nitrile gloves do not require transport warning as the gloves are not classified as hazardous.

Further safety information can be obtained from the material safety data sheet (available on request).